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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,725	02/25/2004	Kirk D. Swenson	3896-031736 (P-6004)	2750

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EXAMINER

TOWA, RENE T

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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11/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.		Applicant(s)	
	10/786,725		SWENSON ET AL.	
	Examiner		Art Unit	
	Rene Towa		3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office action is responsive to an amendment filed August 24, 2007. Claims 1-9 and 23-26 are pending. Claims 10-22 and 27-38 have been cancelled. No claim has been added. No claim has been amended.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4 & 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Odell et al. (US 5,662,617).

In regards to claim 1, Odell et al. disclose(s) a holder assembly comprising:

a holder housing 34 for receiving a sample collection tube within a rearward end,
a forward end of the holder housing 34 including;

a needle receiving port for receiving a needle cannula 12 therein and

an annular skirt extending about the needle receiving port; and

a safety shield 38 pivotably attached to a collar 48, said collar 48 having an opening therethrough for receiving a needle cannula 12 therethrough, the collar 48 being received between the annular skirt and the needle receiving port of the holder housing 34 such that the safety shield 38 is capable of being pivoted over at least a portion of a needle received within the needle receiving port of the holder housing 34,

wherein the safety shield 38 and the collar 48 are axially rotatable with respect to the holder housing 34 about an axis of the holder housing 34, such that the safety shield 38 and the collar 48 can be radially rotated to a desired position around a needle 12 received within the needle receiving port and around the axis of the holder housing 34 without axial movement of the collar along the axis (see figs. 1-34; col. 7, lines 1-30).

In regards to claim 2, Odell et al. disclose(s) a holder assembly wherein the collar 48 is annular (see fig. 4).

In regards to claim 9, Odell et al. disclose(s) a holder assembly wherein the shield 38 and the collar 48 are integral and attached through a living hinge 56 (see figs. 4 & 6; col. 10, lines 38-59).

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. **Claims 3-4** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Odell et al. ('617).

In regards to claim 3, Odell et al. disclose(s) a holder assembly wherein the shield 38 comprises a rearward end, a forward end, a longitudinal opening in the forward end for receiving a needle 12, and a hanger bar (130, 140) on the rearward end adapted to connect the safety shield 38 to the collar 48 (see figs. 18-23).

In regards to claim 4, Odell et al. disclose(s) a holder assembly wherein the collar 48 comprises a hook arm 103a,b (i.e. defined in part by either holes 136 or 146), the hook arm 103a,b engages the hanger bar (130, 140) for connecting the safety shield 38

to the collar 48 whereby there is an interface fit between the hanger bar (130, 140) and the hook arm 103a,b (see figs. 18-23).

Although Odell et al. teach a pivot assembly comprising a hook arm and hanger (see figs. 34-35), Odell et al. disclose a holder assembly, as described above, that fails to explicitly teach a pivot assembly wherein the hanger bar is part of the safety shield and the hook arm is part of collar.

However, since Odell et al. teach a pivot mechanism between the safety shield and the hook arm, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a holder assembly similar to that of Odell et al. with a pivot assembly wherein the hanger bar is part of the safety shield and the hook arm is part of collar since such a modification would amount to a mere reversal of parts that serves the same purpose as the pivot of Odell et al. Moreover, it has previously been held that merely reversing parts is not patentable--*In re Gazda*, 219 F. 2d 449, 452, 104 USPQ 400, 402 (CCPA 1955).

4. **Claims 3-4 & 7** are rejected under 35 U.S.C. 103(a) as obvious over Odell et al. ('617) in view of Kobayashi (US 6,695,819).

Although Odell et al. teach a pivot assembly comprising a hook arm and hanger (see figs. 34-35), Odell et al. disclose a holder assembly, as described above, that fails to explicitly teach a pivot assembly wherein the hanger bar is part of the safety shield and the hook arm is part of collar.

However, Kobayashi discloses a holder assembly wherein the hanger bar 78 is part of the safety shield 70 and the hook arm 36 is part of collar 30 (see figs. 2, 4, 8-9 & 12).

In regard to **claims 3-4**, since Odell et al. teach a pivot mechanism between the safety shield and the hook arm, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a holder assembly similar to that of Odell et al. with a pivot assembly wherein the hanger bar is part of the safety shield and the hook arm is part of collar similar to that of Kobayashi since such a modification would amount to a mere reversal of parts that serves the same purpose as the pivot of Odell et al. Moreover, it has previously been held that merely reversing parts is not patentable--*In re Gazda*, 219 F. 2d 449, 452, 104 USPQ 400, 402 (CCPA 1955).

In regards to **claim 7**, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a holder assembly similar to that of Odell et al. as modified by Kobayashi, above, with an annular skirt that encloses an open end of the hook arm since such a modification would amount to an obvious design choice that would serve the same purpose of pivoting the safety shield.

5. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Odell et al. ('617) in view of Gyure et al. (US 5,681,295)).

Odell et al. teach a holder assembly, as described above, that fails to explicitly teach a collar having one or more slits in a rearward portion thereof.

However, Gyure et al. disclose a holder assembly comprising a collar having one or more slits in a rearward portion thereof (see figs. 3-4; col. 3, lines 50-67; col. 4, lines 1-27).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a holder assembly similar to that of Odell et al. with one or more slits similar to that of Gyure et al. in order to provide the collar with some flexibility to allow it to be easily snapped into place (see Gyure et al., col. 4, lines 20-27).

6. **Claims 5-7 are** rejected under 35 U.S.C. 103(a) as being unpatentable over Odell et al. ('617) in view of Hollister ('311).

Odell et al. disclose a holder assembly, as described above, that fails to explicitly teach an assembly wherein the collar attaches to the forward end of the holder housing, or wherein the collar includes outwardly extending protrusion.

However, Hollister discloses a holder assembly comprising a collar 18 that attaches to the forward end of the holder housing 2 (see figs. 3-4).

Since both Odell et al. and Hollister pertain to holder assemblies wherein the safety shield and the collar are axially rotatable with respect to the holder housing about an axis of the holder housing without axial movement of the collar along the axis, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a holder assembly similar to that of Odell et al. with a collar that attaches to the forward end of the holder housing similar to that of Hollister since such a modification would serve the same purpose of obtaining a holder

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assemblies wherein the safety shield and the collar are axially rotatable with respect to the holder housing about an axis of the holder housing without axial movement of the collar along the axis.

7. **Claims 23-26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Odell et al. ('617) in view of Kobayashi ('819) further in view of Hollister ('311).

In regards to **claim 23**, Odell et al. disclose(s) a holder assembly comprising:

a holder housing 34 adapted to receive a sample collection tube within a rearward end, a forward end of the holder housing 34 including a needle receiving port for receiving a needle cannula 12 therein, the holder housing 34 having an annular skirt extending from the forward end (see figs. 1-34; col. 7, lines 1-30)

In regards to **claim 24**, Odell et al. disclose(s) a holder assembly wherein the collar 48 is rotatable about an axis of the holder housing 34 (see col. 7, lines 1-30).

In regards to **claim 25**, Odell et al. disclose(s) a holder assembly wherein the collar 48 further comprises an interior opening for receiving a needle cannula 12 therein (see fig. 1).

In regards to **claim 26**, Odell et al. disclose(s) a holder assembly wherein the interior opening includes structure for engagement with corresponding mating structure on a needle cannula assembly (see fig. 1).

Although Odell et al. teach a pivot assembly comprising a hook arm and hanger (see figs. 34-35), Odell et al. disclose a holder assembly, as described above, that fails to explicitly teach a pivot assembly wherein the hanger bar is part of the safety shield

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and the hook arm is part of collar or an assembly wherein the collar attaches to the forward end of the holder housing.

However, Kobayashi discloses a holder assembly wherein the hanger bar 78 is part of the safety shield 70 and the hook arm 36 is part of collar 30 (see figs. 2, 4, 8-9 & 12).

In regards to **claim 23**, since Odell et al. teach a pivot mechanism between the safety shield and the hook arm, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a holder assembly similar to that of Odell et al. with a pivot assembly wherein the hanger bar is part of the safety shield and the hook arm is part of collar similar to that of Kobayashi since such a modification would amount to a mere reversal of parts that serves the same purpose as the pivot of Odell et al. Moreover, it has previously been held that merely reversing parts is not patentable--*In re Gazda*, 219 F. 2d 449, 452, 104 USPQ 400, 402 (CCPA 1955).

Similarly, since both Odell et al. and Hollister pertain to holder assemblies wherein the safety shield and the collar are axially rotatable with respect to the holder housing about an axis of the holder housing without axial movement of the collar along the axis, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a holder assembly similar to that of Odell et al. as modified by Kobayashi, above, with a collar that attaches to the forward end of the holder housing similar to that of Hollister since such a modification would serve the same purpose of obtaining a holder assemblies wherein the safety shield and the collar

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are axially rotatable with respect to the holder housing about an axis of the holder housing without axial movement of the collar along the axis.

Response to Arguments

3. Applicant's arguments filed August 24, 2007 have been fully considered but are moot in view of the new grounds of rejection(s).

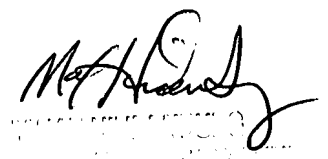
Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RTT/

A handwritten signature in black ink, appearing to read "Max Hindenburg", is written over a faint, rectangular official stamp. The signature is fluid and cursive.